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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,798	11/02/2000	Amanda Johanne Kiliaan	BO 44102 ACW	2164

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/25/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/703,798	KILIAAN ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's Request for Continued Examination filed April 24, 2003 has been received and entered into the case. Claims 34 – 38 have been added. Claims 19 – 38 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19 – 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 and its dependents are drawn to a composition however are rendered vague and indefinite because the claim recites "comprising", "consisting of" and "containing", which have different meanings under 35 USC 112,2. Specifically, by reciting both open ended and close ended transitional phrases, the scope of the claim is not clearly delineated.

Claim 19 is further confusing because while fraction (a) requires "at least one of" the named fatty acids, the claim also requires a ratio between particular fatty acids. It is unclear if more than one fatty acid must be present, or if one from each grouping ([EPA, DHA, DHGLA, AA] and [linoleic, alpha linoleic]) must be present to meet the limitation of the claim.

Claim 19 is rendered vague and indefinite for requiring a ratio of fatty acids and not reciting the ratio as a ratio ("is above 0.4"). Moreover, it is unclear what the required ratio of fatty acids is.

Claim 27 is rendered vague and indefinite because it is unclear if fraction (c) rather comprises zinc and copper, or further comprises zinc and copper.

Claim 27 is also indefinite for requiring a ratio without reciting the ratio as a ratio ("is between 5 to 12"). It is unclear what ratio of zinc to copper is required to meet the claim.

Claims 34 and 35 are confusing because it is unclear if "about 2.5 to 5.5 wt/wt" is meant as a ratio of omega 3 to omega 6 fatty acids (i.e. 2.5 omega 3 : 5.5 omega 6) or if the limitation is meant as a range.

Claim 35 and its dependents are drawn to a composition however are rendered vague and indefinite because the claim recites "comprising", "consisting of" and "containing", which have different meanings under 35 USC 112,2. Specifically, by reciting both open ended and close ended transitional phrases, the scope of the claim is not clearly delineated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 19 – 20, 22 – 23, 26, 30 – 31, and 33 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin (US 4810497), della Valle et al. (US 4595680) and Fugh-Berman et al. (1999).

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) at least one of EPA, DHA, DHGLA, AA, linoleic or alpha linoleic acid, with a specified ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (d) citrates or citric acid; or (h) ginkgo biloba extract. The fatty acids are omega-3 and omega-6 fatty acids selected from EPA, DHA, AA and DGLA. Fraction (c) further comprises one of SAMe, choline, betaine or copper, the composition is a nutritional supplement, and the fatty acids are in a specific ratio. Specifically, the composition comprises at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate. Applicant additionally claims a

composition comprising (a) omega 3 and omega 6 fatty acids in a specific ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc; and further comprising citrates or citric acid.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with

a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

6. Claims 19 – 20, 22 – 24, 26, 30 – 31, 33 – 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Taiyo Fishery Co LTD (DERWENT 1990-302732).

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) at least one of EPA, DHA, DHGLA, AA, linoleic or alpha linoleic acid, with a specified ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (d) citrates or citric acid; or (h) ginkgo biloba extract. The fatty acids are omega-3 and omega-6 fatty acids selected from EPA, DHA, AA and DGLA. Fraction (b) is phosphatidylcholine, phosphatidylethanolamine and phosphatidylserine and fraction (c) further comprises one of SAMe, choline, betaine or copper, the composition is a nutritional supplement, and the fatty acids are in a specific ratio. Specifically, the composition comprises at least 120 mg long chain fatty acids, 200 mg

phospholipids, 200 micrograms folic acid, and 500 mg citrate. Applicant additionally claims a composition comprising (a) omega 3 and omega 6 fatty acids in a specific ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine, specifically phosphatidylcholine, phosphatidylethanolamine and phosphatidylserine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc; and further comprising citrates or citric acid.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Taiyo Fishery Co teaches compositions of phosphatidylcholine and phosphatidylethanolamine for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although

the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

7. Claims 19 – 23, 26, 30 – 31 and 33 – 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Yu et al. (US 5177082).

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) at least one of EPA, DHA, DHGLA, AA, linoleic or alpha linoleic acid, with a specified ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (d) citrates or citric acid; (e) huperzine A; or (h) ginkgo biloba extract. The fatty acids are omega-3 and omega-6 fatty acids selected from EPA, DHA, AA and DGLA. Fraction (c) further comprises one of SAMe, choline,

betaine or copper, the composition is a nutritional supplement, and the fatty acids are in a specific ratio. Specifically, the composition comprises at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate. Applicant additionally claims a composition comprising (a) omega 3 and omega 6 fatty acids in a specific ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc; and further comprising citrates or citric acid; or huperzine A.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Yu teaches compounds for treating dementia (abstract) wherein huperzine A is a representative compound (col.4 line 24-25).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the

cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

8. Claims 19 – 20, 22 – 23, 25 – 26, 30 – 31 and 33 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Smith et al.(US 6008221).

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) at least one of EPA, DHA, DHGLA, AA, linoleic or alpha linoleic acid, with a specified ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (d) citrates or citric acid; or (h) ginkgo biloba extract. The fatty acids are omega-3 and omega-6 fatty acids selected from EPA,

DHA, AA and DGLA. Fraction (c) further comprises one of SAMe, choline, betaine or copper; wherein (c) contains at least folic acid and vitamin B6; the composition is a nutritional supplement, and the fatty acids are in a specific ratio. Specifically, the composition comprises at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate. Applicant additionally claims a composition comprising (a) omega 3 and omega 6 fatty acids in a specific ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc; and further comprising citrates or citric acid.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Smith teaches compositions for treating Alzheimer's disease, comprising folic acid, vitamin B12 (abstract), betaine, and/or vitamin B6 (col.2 line 43-52).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

9. Claims 19 – 20, 22 – 23, 26 – 27, 31 and 33 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Hutterer (US 4867219).

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) at least one of EPA, DHA, DHGLA, AA, linoleic or alpha linoleic acid, with a specified ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol,

phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (d) citrates or citric acid; or (h) ginkgo biloba extract. The fatty acids are omega-3 and omega-6 fatty acids selected from EPA, DHA, AA and DGLA. Fraction (c) further comprises one of SAMe, choline, betaine or copper; or (c) comprises zinc and copper in a specific ratio; the composition is a nutritional supplement, and the fatty acids are in a specific ratio. Specifically, the composition comprises at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate. Applicant additionally claims a composition comprising (a) omega 3 and omega 6 fatty acids in a specific ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc; and further comprising citrates or citric acid.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Hutterer teaches compositions comprising choline, zinc and copper (abstract) in specific amounts and ratios (col.4 line 13-23) for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

10. Claims 19 – 20, 22 – 23, 25 – 27 and 30 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman, Smith, Hutterer and Glick (US 5004615).

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) at least one of EPA, DHA, DHGLA, AA, linoleic or alpha linoleic acid, with a specified ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (d) citrates or citric acid; or (h) ginkgo biloba extract. The fatty acids are omega-3 and omega-6 fatty acids selected from EPA, DHA, AA and DGLA. Fraction (c) further comprises one of SAMe, choline, betaine or copper; contains at least folic acid and vitamin B6; or comprises zinc and copper in a specific ratio. The composition is a nutritional supplement and the fatty acids are in a specific ratio. Specifically, the composition comprises at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate. More specifically, at least 20 mg EPA, 50 mg DHA, 50 mg AA, 200 mg phospholipids, 200 micrograms folic acid, 100 mg magnesium, 5 mg zinc, 2 mg vitamin B6, 2 micrograms vitamin B12 and 1g citrate. Applicant additionally claims a composition comprising (a) omega 3 and omega 6 fatty acids in a specific ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc; and further comprising citrates or citric acid.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Smith teaches compositions for treating Alzheimer's disease, comprising folic acid, vitamin B12 (abstract), betaine, and/or vitamin B6 (col.2 line 43-52).

Hutterer teaches compositions comprising choline, zinc and copper (abstract) in specific amounts and ratios (col.4 line 13-23) for treating Alzheimer's disease (abstract).

Glick teaches administering dietary supplements of magnesium for preventing and controlling dementia and memory loss (abstract, col.3).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established

proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

11. Claims 19 – 20, 22 – 23, 26, 28 – 31 and 33 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Rabien (DE 4309217).

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) at least one of EPA, DHA, DHGLA, AA, linoleic or alpha linoleic acid, with a specified ratio; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (d) citrates or citric acid; (f) one or more selected from carnitine, vitamin B1, B5 and coenzyme Q10; (g) one or more antioxidants selected from vitamin C, E, lipoic acid, selenium salt and carotenoids; or (h) ginkgo biloba extract. The fatty acids are omega-3 and omega-6 fatty acids selected from EPA, DHA, AA and DGLA. Fraction (c) further comprises one of SAMe, choline, betaine or copper, the composition is a nutritional supplement, and the fatty acids are in a specific ratio. Specifically, the composition comprises at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate. Applicant additionally claims a composition comprising (a) omega 3 and omega 6 fatty acids in a specific ratio; (b) at least two different

phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc; and further comprising citrates or citric acid.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Rabien teaches compositions comprising alpha lipoic, panthothenic acid (vitamin B5) and vitamin E for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in

the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
August 20, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER